

REMARKS/ARGUMENTS

Claims 1-24 and 26-33 are pending in the present application. No amendment is currently made to any of the pending claims. It is respectfully requested that the Examiner reconsider the rejection of the claims in view of the following remarks.

It is gratefully acknowledged that claims 1-22, 24, and 26-32 are allowed. But claims 23 and 33 are rejected. Applicants respectfully traverse.

I. Rejection of claim 23 under 35 U.S.C. 112, second paragraph, as being indefinite

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite. *See* page 2, item 1 of the Office Action. According to the Examiner, claim 23 fails to set forth the metes and bounds of the claim due to the expression “a solvate or hydrate form of olanzapine.” The specific reason for this rejection is not clear. As Applicants explained in the previously submitted Amendment, a person of ordinary skill in the art would have no difficulty to understand the meaning of the terms “hydrate” or “solvate”, which is commonly used in the art. There is no ambiguity concerning the term “hydrate” or “solvate.” Nor does the Examiner provide any basis to support that the use of these two terms affects clear definition of the metes and bounds of the claimed invention. In contrast, the Examiner appears to agree that the meaning of these two terms is clear. For example, at page 4, lines 4-5 of the Office Action, the Examiner states “solvates are crystalline organic solids made up of molecules that are packed or ordered in a specific arrangement.”

Applicants note that in the previous Office Action dated October 2, 2009, page 3, item 1.d), the Examiner states: “Claim 23 is vague and indefinite in that it is not known what is meant by ‘solvate or hydrate’ such that it is not known which solvate or hydrate this refers to.” This statement appears to suggest that a specific solvate or hydrate must be specified in the claims.

But the law does not prohibit the use of a generic term in a claim. Rather, a generic term is commonly used in a claim, such as metal vs. steel, copper etc. Here, it is clear from claim 23 itself that the term “hydrate” is a generic concept, which covers any specific hydrate form. The Examiner also appears to correctly understand that “hydrate” is a generic term, when the Examiner discusses that the specification does not provide adequate support for the generic concept of “hydrate” under 35 U.S.C. § 112, first paragraph.

Moreover, as discussed above, Section 112, second paragraph, deals with the clarity and definiteness of a claim. Nothing in claim 23, including the term “hydrate” creates any ambiguity. As to whether the use of a generic term, such as “hydrate”, is supported by the specification, it may pertain to the Written Description or Enablement requirement under 35 U.S.C. § 112, first paragraph, which will be discussed separately below, but not to the Definiteness requirement under 35 U.S.C. § 112, second paragraph.

The Examiner also states “there is no evidence that hydrates or solvates other than the isopropanol/water solvate, of these compounds actually exist.” See page 3, lines 6-7 of the Office Action. First, whether the hydrates or solvates exists has nothing to do with whether claim 23 is definite. As stated above, the meaning of “hydrate” and “solvate” is clear to a person of ordinary skill in the art. Second, the Examiner’s statement is factually incorrect. For example, pages 20-22, Examples 8-12 of the specification discuss in detail the preparation of olanzapine methylene chloride solvate, which is not isopropanol/water solvate.

Additionally, the term “solvate” is not currently recited in claim 23, the Examiner’s discussion concerning “solvate” does not apply to claim 23.

Based on the foregoing, it is respectfully that the rejection of claim 23 under 35 U.S.C. § 112, second paragraph is withdrawn.

II. Rejection of claim 23 under 35 U.S.C. 112, first paragraph, as not being enabled

Claim 23 is rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification. *See* pages 3-4, item 3 of the Office Action. Applicants disagree.

Claim 23 recites a process for the preparation of a hydrate form of olanzapine comprising dissolving the isopropanol/water mixed solvate of olanzapine according to claim 1, and crystallizing or precipitating the hydrate form of olanzapine. The claim language itself actually provides sufficient guidance for a person ordinary skill in the art to practice the claimed invention. For example, a person ordinary skill the art may add the starting material isopropanol/water mixed solvate of olanzapine according to claim 1, which has been allowed, to a solvent, e.g., water, so that the starting material is dissolved, and then adjust the temperature, so that the hydrate form of olanzapine precipitates. The specification provides more detailed information concerning how to making a hydrate form of olanzapine by using the isopropanol/water mixed solvate as the starting material. *See* page 13, lines 7-11 and pages 20-22, Examples 8-12. It is apparent from the specification that the most important feature of the present invention is to use the isopropanol/water mixed solvate as the starting material. Once starting material is selected, a person of ordinary skill in the art would have no difficulty in making a hydrate form based on the information provided in the present application, without the need of engaging undue experimentation.

Therefore, it is respectfully requested that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

III. Rejection of claim 33 under 35 U.S.C. 112, first paragraph, as not being enabled

Claim 33 is rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification. *See* page 4, last paragraph of the Office Action. Applicants disagree.

Claim 33 is directed to a process of making a solvate. The present application provides specific examples of making a solvate of olanzapine using the isopropanol/water mixed solvate of olanzapine of claim 1 as the starting material (*see* pages 2-22, Examples 8-12). Without the need of engaging undue experimentation, a person of ordinary skill in the art will be able to practice the present invention by dissolving the isopropanol/water mixed solvate of olanzapine according to claim 1, and crystallizing or precipitating the solvate form of olanzapine, based on the present specification.

As to the use of the generic term “solvate”, the law does not prohibit the use of a generic term in a claim. *See* MPEP 2164.02 (“For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.”)

MPEP 2163.05 states: “On the other hand, there may be situations where one species adequately supports a genus. *See, e.g., In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326-27 (CCPA 1981) (disclosure of a single method of adheringly applying one layer to another was sufficient to support a generic claim to “adheringly applying” because one skilled in the art reading the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered.)”

In *re Herschler*, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979) (quoted by MPEP2163.05), the court states that disclosure of corticosteroid in DMSO is sufficient to support claims drawn to a method of using a mixture of a "physiologically active steroid" and DMSO because "use of known chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Similarly, here, the disclosure of crystallizing the starting material isopropanol/water mixed solvate in a manner auxiliary to the invention is sufficient in leading one having ordinary skill in the art to make a solvate form of olanzapine. A person of ordinary skill in the art would have no difficulty in predicting the operability of making any specific solvate from the starting material isopropanol/water mixed solvate. See also, *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973) (quoted by MPEP2163.05) (the phrase "air or other gas which is inert to the liquid" was sufficient to support a claim to "inert fluid media" because the description of the properties and functions of the air or other gas segmentizing medium would suggest to a person skilled in the art that appellant's invention includes the use of "inert fluid" broadly.).

Therefore, it is respectfully requested that the rejection of claim 33 under 35 U.S.C. § 112, first paragraph be withdrawn.

Based on the foregoing, favorable consideration and a Notice of Allowance are earnestly solicited. Should the Examiner disagree, Applicant respectfully requests a telephonic interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

If any other fees or charges are required at this time, they may be charged to our Patent and
Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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